

**Indiana State Department of Health  
Pre-Event Smallpox Vaccination Plan  
December 9, 2002**

**(This plan was approved by the Centers for Disease Control and Prevention (CDC) as of December 15, 2002. It is a working document, to which changes are continuing to be made. These changes will be posted as they are approved by the CDC.)**

## **Section 1. Organization and Management**

### **Identification of Management Personnel**

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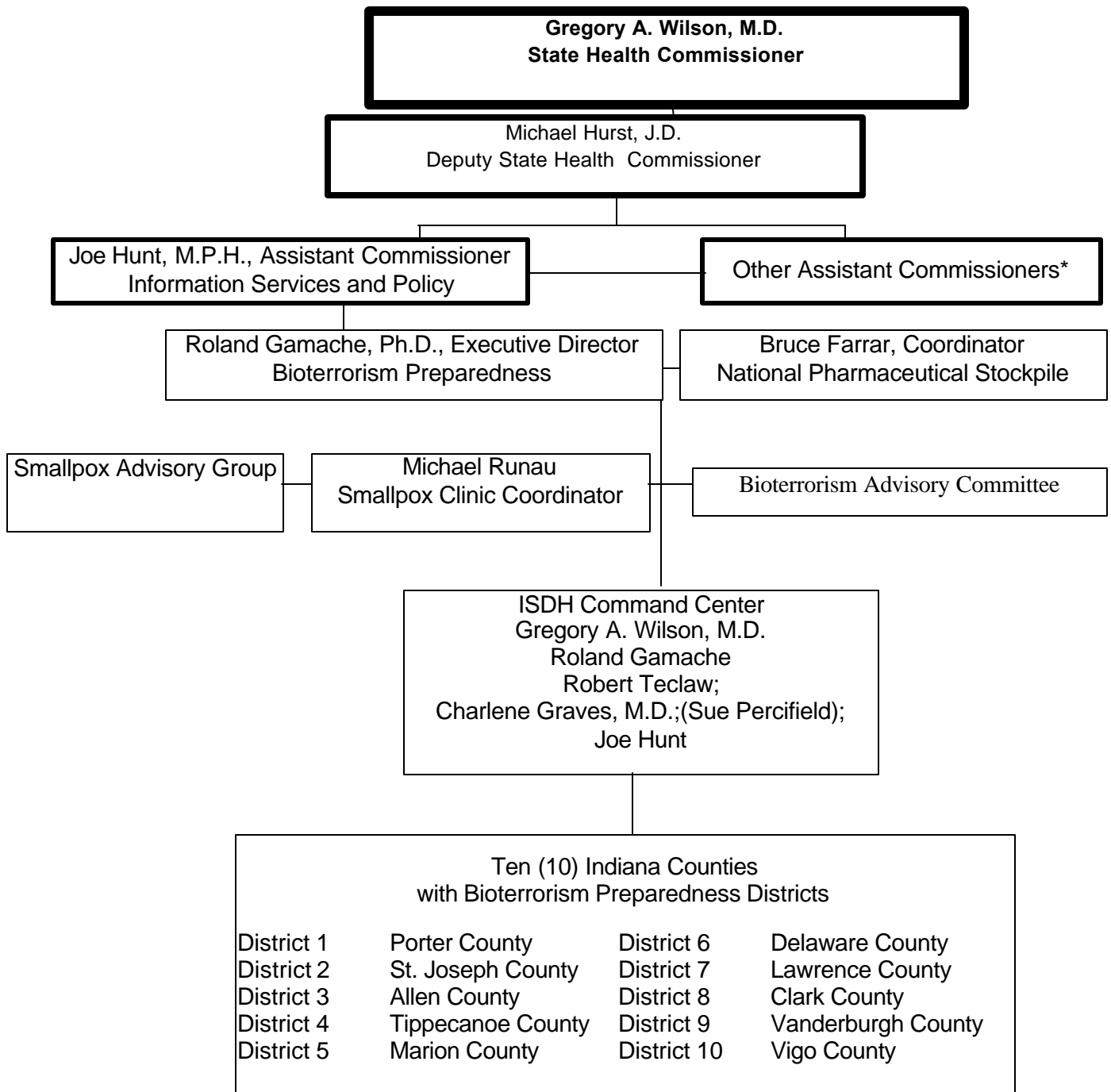
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### **PROGRAM IMPLEMENTATION TIMELINE:**

A Microsoft Project plan that details the pre-event activities as described in the guidance is provided in Appendix A. The activities are group by function and document the timeline for pre-event smallpox vaccinations. It was assumed in the planning process that the vaccine would become available on January 15, 2003. This date and the associated activities would move as this start date is changed.

Following an official announcement, the Indiana State Department of Health would complete the initial vaccination of authorized and identified personnel within thirty (30) working days based on this planning process.

## 1. Organization and Management



\*Operational Services  
 Community Health Development Services  
 Children & Family Health Services  
 Health Care Regulatory Services

☆☆: See List for Details and Assignments

## **2. Identification of Public Health Response Teams**

### **Number of Teams:**

The Indiana State Department of Health (ISDH) proposes that the State of Indiana organize and train a minimum of three Public Health Response Teams. One of these teams will be organized solely from ISDH staff. The second team will be organized by the Marion County Health Department (MCHD) from its staff and staff from other local public or private agencies in the Indianapolis metropolitan area. The third team will be organized by the Fort Wayne/Allen County Health Department from its staff and staff from other local public and private agencies in the Fort Wayne area, with possible augmentation from the ISDH. Both Indianapolis and Fort Wayne are MMRS recipients. The two local Coordinating Agency teams would be responsible for responding to suspected and confirmed smallpox cases in their Bioterrorism Preparedness Districts, while the ISDH would be responsible for the eight other Bioterrorism Preparedness Districts in Indiana. The other districts have been provided guidance on the organization of Public Health Response Teams, and those that are capable will work to organize their own teams with augmentation from the ISDH as needed. However, due to the limited number of public health workers in many of the local Bioterrorism Preparedness Districts, some districts will not be able to organize a team. At least three Public Health Response Teams will be vaccinated during Phase 1 vaccination.

### **Proposed Composition:**

A public health response team consists of a minimum of 22 individuals, 11 primary team members and 11 backup team members. The primary team members are the first to respond. The backup team members respond if a primary member is not available, or on an as-needed basis, if the response continues for more than a few days or if it must go to 24/7 shift operations.

The staff positions follow:

#### **Medical Expert (1 + 1 backup)**

Role: Responsible for overall leadership of team. Responsible for consultation with physicians and others as to appropriate diagnostic, treatment, and control measures.

Qualifications: A physician, preferably with infectious disease and epidemiological experience.

#### **Lead Smallpox Investigator (1 + 1 backup)**

Role: Lead responsibility for investigating smallpox cases.

Qualifications: A high level of skill and experience in case and outbreak investigation.

#### **Smallpox Surveillance Investigator (1 + 1 backup)**

Role: Lead responsibility for implementing active surveillance for new cases and for supporting the Lead Smallpox Investigator in case investigation.

Qualifications: Skill and experience in the surveillance of infectious disease and case/outbreak investigation.

Contact Tracers (3 + 3 backup)

Role: Responsible for finding and communicating with each contact of a case, and for case investigation if the number of cases to investigate becomes too unwieldy for investigators to handle.

Qualifications: Skill and experience in contact tracing and some skill or experience in case/outbreak investigation.

Contact Monitors (3 + 3 backup)

Role: Responsible for monitoring health of contacts. This would be done primarily by telephone, but some face-to-face communication with the contact(s) may be necessary. These monitors will also act as general support to the other team members.

Qualifications: Background in public health, but no specific skill or experience is required.

Vaccinator (1 + 1 backup)

Role: Responsible for vaccinating contacts of a case as they are located, prior to or in conjunction with more extensive ring or mass vaccination efforts.

Qualifications: A nurse, physician, or other individual that can legally give immunizations in Indiana, preferably with some experience in mass and ring vaccination efforts.

Support Staff (1 + 1 backup)

Role: Responsible for support duties such as data entry, ensuring paper work is completed and filed with appropriate agencies, etc.

Qualifications: General office and computer skills.

The team is not limited to the number of individuals listed above. The above listing will be considered the minimum level of staffing necessary. Additional backup staff in any of the roles is appropriate. The ISDH Laboratories will provide laboratory support for all teams. Licensed professional members of the team will be trained in clinical sample collection procedures.

Timeline

Selection of Teams

December 15, 2002 ISDH, Marion County Health Department, and Fort Wayne/Allen County Health Department finalize team membership by naming participants.

December 30, 2002 Other local Bioterrorism Preparedness Districts report to the ISDH on capacity to organize Public Health Response Teams.

### Vaccination of Teams

(Day 1 is day that vaccine becomes available to ISDH)

December 3, 2002      Satellite presentation to all local health departments (LHD) and ISDH staff on smallpox and smallpox vaccination.

Day 3                      Provide vaccine information and informed consent documentation to all named members of Public Health Response Teams.

Before Day 5            Conduct vaccination clinic at the ISDH for all ISDH public health response team staff (in conjunction with vaccination team staff).

Before Day 7            Conduct vaccination clinics in Marion and Allen Counties to vaccinate those LHD public health response team staff (in conjunction with health care response team staff).



### **3. Identification of Healthcare Response Teams**

#### **a) Collaboration with local health agencies:**

Information on the development of the Healthcare Response Teams was produced in conjunction with the Indiana Hospital&Health Association (IHHA). The IHHA distributed the information to all of the acute care licensed hospitals in the State of Indiana. In addition, the Indiana State Department of Health (ISDH) distributed the same information to the Coordinating Agency local health departments (LHD). The American Hospital Association (AHA) Disaster Readiness Advisory #9 (which included the ACIP recommendation) was included with that mailing. All Indiana entities working on the development of the Healthcare Response Teams used the same information base.

Additional information on the CDC Bioterrorism *“A National Immunization Program and Public Health Training Network Satellite Broadcast and Webcast”* was distributed to the acute care hospital Bioterrorism Contacts.

E-mail and phone communications with the hospitals, IHHA, and the Coordinating Agency LHDs are planned on a regular basis to keep them current on activities and timelines.

#### **b) Number of Hospitals and Healthcare Response Teams:**

“Number” acute care hospitals responded and volunteered to participate in the pre-event smallpox vaccination program. The 10 Bioterrorism Preparedness District Coordinating Agency LHDs recommended “number,” and, after consulting with the Bioterrorism Coordinator for Hospital Preparedness and the IHHA, the State Health Commissioner will make the final selection of the teams and locations.

#### **c) Policy Defining Hospital Responsibilities:**

In cooperation with IHHA, the following policy was developed. All hospitals will be requested to accept the concepts and adopt them in a policy particular to their individual hospital.

- ISDH and the Coordinating Agency LHDs will provide vaccinators, vaccine, and needed materials for the initial pre-event vaccination of the hospital’s healthcare response team. The hospitals should provide facility space for the vaccination clinic site when asked by the LHD and, in addition, space for education and screening of their staff who have volunteered to be vaccinated as a member of the hospital’s healthcare response team. The hospital should provide trained staff to perform adverse event evaluation, treatment for adverse events, daily vaccination site management, and evaluation of “Takes” for all members of the hospital’s healthcare response team.

After there has been proper training of hospital staff and the vaccine and supplies are more readily available, the hospital could assume all responsibility for staff vaccinations. The hospitals will also be requested to assist in a community-wide vaccination when authorized.

**d) Number and occupational types of healthcare personnel to be vaccinated:**

The occupation types of healthcare personnel to be vaccinated follow:

1. Emergency Room staff, including both physicians and nurses. (850)
2. Intensive Care Unit staff, including both physicians and nurses. In hospitals that care for infants and children, this encompasses pediatricians, pediatric intensivists, and pediatric emergency room physicians and nurses. (200)
3. General Medical Unit staff, including physicians, internists, pediatricians, obstetricians, and family physicians in institutions where these individuals are the essential providers of primary medical care. (550)
4. Medical house staff (i.e., selected medical, pediatric, obstetric, and family physicians). (50)
5. Medical subspecialists, including infectious disease specialists (this may involve the creation of regional teams of subspecialists [e.g., local medical consultants with smallpox experience, dermatologists, ophthalmologists, pathologists, surgeons, anesthesiologists in facilities where intensivists are not trained in anesthesia] to deliver consultative services). (300)
6. Infection control professionals (ICP). (10)
7. Respiratory therapists. (150)
8. Radiology technicians. (75)
9. Security staff. (100)
10. Transport (100)
11. Other (375)

The total number of healthcare workers to be vaccinated is (2,760).

**e) Timeline for selection of hospitals and team members:**

December 9, 2002	Hospitals to participate will be selected from the list provided by the Coordinating Agency LHDS.
December 16, 2002	The selected hospitals and their participation will be verified by contact from the Coordinating Agency LHD and the ISDH.

December 23, 2002

Participating hospitals to provide the Coordinating Agency LHD, the ISDH, and the IHHA the list of employee names, by occupation, who have been screened and who have agreed to be vaccinated.

#### **4. Selection of Clinic Sites and Vaccination Teams**

##### **a) Designate a few, fixed, geographical sites to minimize wastage and maximize security of vaccine**

The fixed sites for vaccine storage will be designated by the 10 Coordinating Agency local health departments located within the local Bioterrorism Preparedness Districts and will be communicated to the ISDH for delivery and transportation issues.

##### **b) Number and location of clinic sites**

There will be a minimum of 10 and a maximum of 20 clinic sites throughout the State of Indiana. The minimum of 10 is to allow for at least one clinic site in each of the 10 local Bioterrorism Preparedness Districts. Specific clinic sites will be determined by the local Bioterrorism Preparedness Districts, and then each District's Coordinating Agency local health department will be responsible for communicating that information to the ISDH. For aid in determining a clinic site location, the ISDH recommends using the Protocol for Mass Prophylaxis as a guide. This Guide outlines how to identify an appropriate clinic site, including, but not limited to, having a large floor space area, ADA accessibility, and adequate sanitary facilities.

##### **c) Timeline for selecting sites and clinic teams**

Week of December 16, 2002 Each local Bioterrorism Preparedness District will develop a preliminary list of potential clinic team members and clinic sites.

Week of December 23, 2002 ISDH and Coordinating Agency local health department in each local Bioterrorism Preparedness District will review and finalize lists of clinic team members and clinic sites.

##### **d) Plan for training clinic teams**

Please refer to Section 9: Training and Education

##### **e) Plan for supervision, management, and evaluation of clinic team members and clinic function**

The supervision and management of clinic team members and clinic function will depend on each site's circumstances. Each set of circumstances will dictate who has the ability to supervise and manage clinic team members and clinic functions. The ISDH recommends that each clinic site have at least one clinic manager and one supply manager. The clinic manager is responsible for overseeing all clinic functions and related problem-solving, as well as evaluating the clinic's efficiency and effectiveness. The supply manager is responsible for overseeing all supply needs, including tracking the vaccine supply, lot numbers, distribution, and wastage, as well as restocking vaccination stations appropriately. Supervising a clinic team and its functions will include the following responsibilities. (Please note: This list is not inclusive; supervision may include other responsibilities.)

- Continuously planning for vaccinations and revising plans as needed.

- Coordinating a core group of representatives from health, administrative, media, public service, education, communication, and nongovernment collaborative organizations.
- Identifying and aiding all persons responsible for operating plan components.
- Securing the capable staff needed to perform all clinic functions.

**f) Intended days and hours of clinic operation**

Days and hours of clinic operation will vary with each individual site and will depend on the level of vaccine distribution at each site, as well. Work schedules for both those operating the clinic and those receiving the vaccination will need to be considered. The ISDH is recommending 10-hour days for clinic sites. A 10-hour clinic day would allow for two 5-hour shifts by the vaccinators. In addition, a 10-hour clinic would expand three shift changes, which would be convenient for health care workers who are to be vaccinated. (Please refer to Section 5: Scheduling for further clinic operation plans and intended days of operation.)

**g) Total number of clinic personnel needed**

The number of clinic personnel needed will vary with each site. The clinic site operators will determine the total number of staff needed to effectively run a clinic site. To refine human resources allocations and to determine the maximum patient flow, public health officials should use the “maxi-vac” software program provided by the CDC to meet the target vaccination goals. To account for no-shows, breaks, surge needs, and other contingencies, the number of staff needed should be increased by approximately 20 percent. The following functions or positions at clinic sites are recommended:

- Forms distribution
- Run orientation video
- Referral
- Medical screeners
- Physician evaluators
- Vaccinators/Witness
- Vaccine preparation/Supply to VS
- Exit review
- Medical records/Data entry
- Clinical manager
- Supply manager
- Clinic flow/QA reviewers/Forms helpers
- Security
- Traffic flow
- Translator (not counted in total clinic staffing estimates)
- Float staff
- EMT
- IT Support

Clinic scheduler/registration, vaccinator assistant, data entry clerk, and a post-vaccination educator are other positions that may be needed for clinic operations.

## 5. Scheduling

a) Total number of persons vaccinated per week – estimated to be between 300 and 600. An explanation for this estimate follows.

It is difficult to estimate the number of persons in Indiana to be vaccinated during Phase 1 of pre-event vaccination. However, for planning purposes, the Indiana State Department of Health (ISDH) staff has considered the range to be from 6,000 to 12,000 total vaccinees.

The State of Indiana has established 10 local Bioterrorism Preparedness Districts. Eventually, there will be a Health Administrator to coordinate public health bioterrorism preparedness efforts in each Bioterrorism Preparedness District and an Epidemiologist to assist local health departments (LHDs) with epidemiological investigations of disease outbreaks. Although both of these professionals will be full-time staff of the ISDH, they will have offices in host LHDs, one per Bioterrorism Preparedness District.

It is unlikely that these Health Administrator positions will be filled in time to assist in developing the pre-event vaccination clinics. Therefore, in the interim, 10 LHDs have been invited to assume Coordinating Agency responsibility for establishing vaccination sites and staffing in their Bioterrorism Preparedness Districts in cooperation with the other LHDs in the District.

With 10 potential clinic sites and approximately 6,000 persons to vaccinate, an average of 600 persons will need to be vaccinated at each site. (Bioterrorism Preparedness District boundaries have been drawn to try to equalize the populations to be served among the 10 Districts). Assuming clinic operation for a 10-hour day and an average time of 5 minutes per vaccination, at least 120 persons can be vaccinated per day per clinic station. This estimate is low, because as novice vaccinators gain confidence, they will be able to increase their pace. With five vaccination stations, all 600 persons could be vaccinated per district in one day.

An additional consideration, however, is the possibility that it may be wise to stagger the vaccinations for the Healthcare Response Team members in each Bioterrorism Preparedness District to assure adequate staffing for the day-to-day operation of hospitals. In that event, the above scheme could be altered to immunize 300 persons during the first week of clinic operation and to immunize the second group of 300 persons during the third and fourth weeks of the proposed 30-day period allowed for vaccination.

To accommodate the higher of our estimated range (i.e., 12,000), ISDH staff would work with the Coordinating Agency LHDs in each Bioterrorism Preparedness District to double the number of vaccination clinic sites per district. With 20 sites, given the above logistics, 600 persons in each Bioterrorism Preparedness District would be vaccinated in

the first week and the second group of 600 would be vaccinated in the third and fourth weeks.

b.) Strategy for scheduling vaccination of Healthcare Response and Public Health Response teams – This will be determined jointly by the ISDH and Coordinating Agency LHDs in each of the 10 Bioterrorism Preparedness Districts.

The strategy for scheduling will be influenced by the total number of persons to be vaccinated and the probable desire of hospitals to stagger the immunizations of their Healthcare Response Team members. As described above, Indiana may have as few as 10 clinic sites. With the staggered vaccination plan, each clinic site would operate during the first week with the goal to immunize approximately 50 percent of Bioterrorism Preparedness District team members. The balance of vaccinations would occur during the third and fourth week.

Appointment scheduling of individual team members will mostly be the responsibility of the Coordinating Agency LHD in their local Bioterrorism Preparedness Districts. Hospitals have been directed to submit the names of their team members to the Coordinating Agency LHD. LHDs within a Bioterrorism Preparedness District are to communicate the names of their team members to the Coordinating Agency LHD, as well. Preferences for first- or third/fourth-week appointments can be accommodated to the extent that appropriate use of 100-dose vaccine vials can be made. The ISDH will aid in coordinating unused vaccine doses by monitoring the number of vaccinations performed per clinic site per day.



## 6. Vaccine Logistics and Security

### a. Points of Contacts:

(1) The NPS Program will ship 50 vials of the Dryvax™ Smallpox vaccine to:  
Indiana State Department of Health

(2) The primary point-of-contact is:  
Roland Gamache, M.B.A., Ph.D.  
Office Telephone: 317.233.7664

Fax: 317.233.7378

(3) The alternate point-of-contact is:  
Mr. Bruce Farrar  
Office Telephone: 317.233.9246

Fax: 317.233.7378

### b. Shipment of Smallpox Vaccine :

(1) One day prior to shipment, ISDH will receive from the CDC-NPS the Smallpox Vaccine Shipment Execution Matrix (Part D, Annex 2, CDC Smallpox Vaccination Program Guidance). This matrix outlines the steps to be followed by CDC-NPS and ISDH POC on arrival of the vaccine package to ISDH.

(2) Upon receipt of the smallpox vaccine, the ISDH will follow the steps outlined in Part B, Annex 2, CDC Smallpox Vaccination Program Guidance. The purpose is to ensure that the vaccine has been maintained at proper temperature during shipment.

(3) The vaccine will arrive in Enduro-Therm containers. The vaccine arrives in kits containing the following: 1 vial of Smallpox Vaccine, 1 vial of diluent for 100 doses, 100 bifurcated needles, one transfer syringe and needle, package inset and lot number stickers. **The entire vaccine kit** will be refrigerated upon arrival. The refrigerator will be monitored at 2 to 8 degrees Celsius. See paragraph d below for monitoring procedures.

(4) The CDC will give a verbal release approval to ISDH, upon confirmation that the cold chain was maintained during the initial distribution. A hard-copy release form will be faxed to the POC in paragraph “a” above.

**c. Safeguarding Smallpox Vaccine :**

**(1) State Site Security.**

**(2) Vaccination Clinic Site Security.** Each vaccine clinic site must have the following security precautions for the vaccine:

- (a) A fixed storage facility
- (b) Controlled access to both the facility and the storage system.
- (c) Surveillance to include cameras or physical prevention of access.

**d. Cold Chain Management of Smallpox Vaccine :**

(1) In order to be acceptable for smallpox vaccine storage, refrigeration units must be validated (refers to a monitored storage system) for maintaining 2-8 degrees Celsius and logged manually every four (4) hours.

(2) One monitor is with the automated sensor monitor alarm. It will automatically call (paragraph c(1)(b)) if temperature deviates from 2-8 degrees Celsius. The second monitor is a TempTale like device that will continuously monitor and record the temperature.

(3) If the primary refrigerator fails, the smallpox vaccine will be moved to a refrigerator operating on generators.

**(4) Vaccination Clinic Site Cold Chain Management.** To properly maintain smallpox vaccine, Vaccination Clinic sites must comply with the following:

(a) Adherence to storage and transportation of product in a 2°-8° Celsius, with a recommended mean temperature of 4° Celsius. **THE SMALLPOX VACCINE SHOULD NEVER BE FROZEN NOR PLACED ON ICE**

(b) Storing.

1 While storing the smallpox vaccine, maintenance of a daily temperature log is crucial. This log should be a recorded temperature from the environment where the vaccine is stored. It should be recorded on or about the same time everyday. While once a day monitoring is minimal, it is recommended that temperature checks occur frequently (six (6) times per day).

2 To facilitate the temperature monitoring, it is required to have a proven method of capturing the proper temperature. A regular refrigerator thermometer with an accurate visual display should work. The storage unit should be a self-refrigerating unit which is properly set to maintain 2°-8° Celsius.

(c) Transportation of the smallpox vaccine can be done as long as strict adherence to cold-chain management is followed.

1 The temperature range for shipment is 2°-8° Celsius. A temperature monitoring/recording device will be accompanying the shipment. This device should be able to check the shipment frequently for accurate temperature monitoring/recording.

2 Prior to using the vaccine, the temperature recorded information should be screened to ensure that the appropriate temperature range was maintained. This information should be captured for future use.

**e. Recovery of Smallpox Vaccine :**

(1) The only vaccine that will be recovered by the NPS Program will be unopened vials validated to have maintained the cold chain.

(2) The Bioterrorism Preparedness District clinic sites will return all unopened vials of the smallpox vaccine by the most direct means available to the clinic.

**f. Redistribution of Smallpox Vaccine :**

(1) After approval to use the smallpox vaccine, the ISDH will begin to transport it to the designated Bioterrorism Preparedness District clinic sites.

(2) Depending upon availability, transportation from the ISDH to the clinics will be by

- (a) Indiana National Guard Helicopter.
- (b) Ground transportation by state vehicle (Indiana State Police or ISDH).
- (c) Overnight delivery by FedEx *Custom Critical* service.

(3) The smallpox vaccine will be shipped in EnduroTherm insulated container with a temperature sensing device. Each clinic site will receive a minimum of one vaccine kit.

(4) Upon receipt of the vaccine and verification of cold chain management, the clinic may begin to reconstitute and vaccinate.

(5) Each Bioterrorism Preparedness District clinic site will follow the cold chain management procedures as outlined in paragraph c(2) and d(4) above.

# ISDH Smallpox Pre-Event Vaccination Project Districts

## District 1

### Porter County Health Department

155 Indiana Ave Rm 104  
Valparaiso, IN 46383-5502  
Gary A Babcoke, MD  
V (219) 465-3525  
F (219) 465-3531

## District 2

### St Joseph County Health Department

227 W Jefferson Blvd Rm 825  
South Bend, IN 46601-1870  
Janice M Carson, MD  
V (574) 235-9750  
F (574) 235-9960

## District 4

### Tippecanoe County Health Department

20 N 3rd St  
Lafayette, IN 47901-1211  
Wendell Riggs, MD  
V (765) 423-9221  
F (765) 423-9154

## District 10

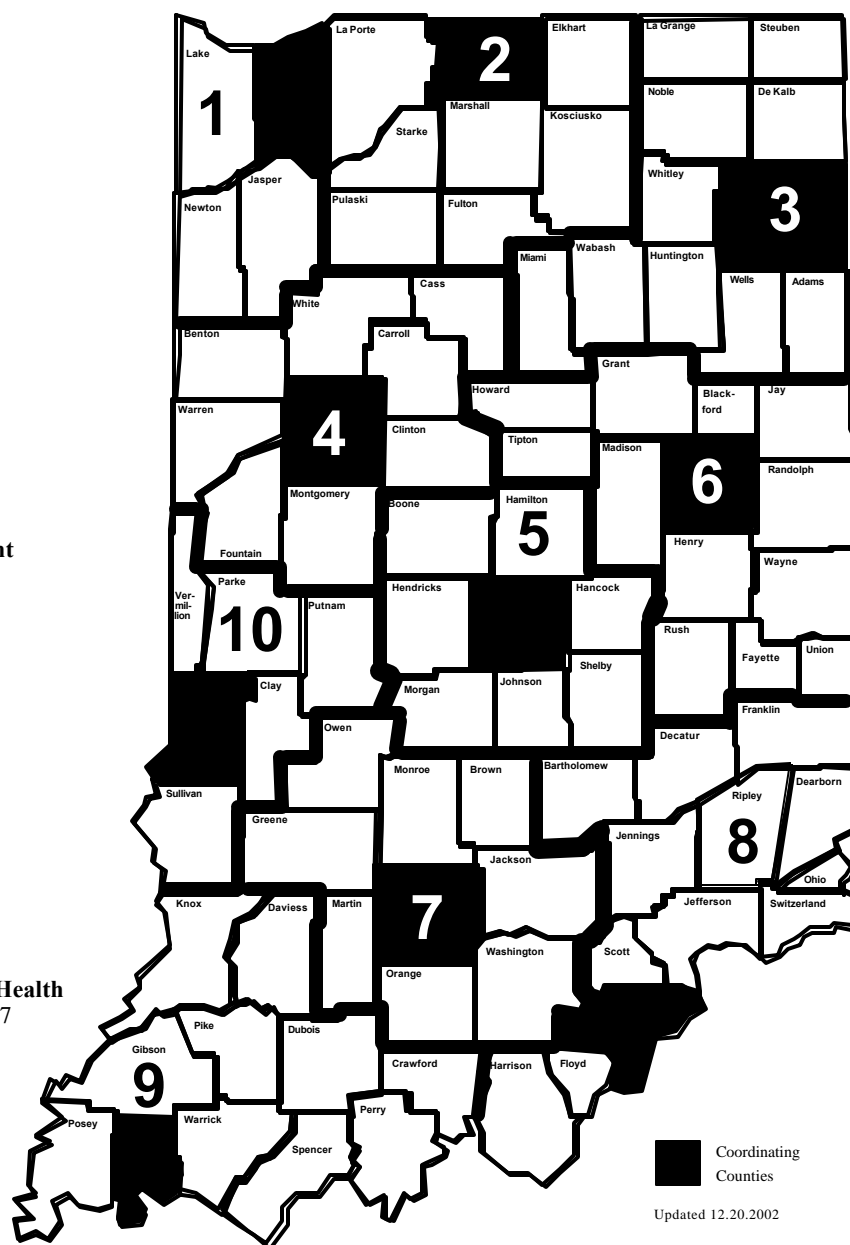
### Vigo County Health Department

147 Oak Street  
Terre Haute, IN 47807-  
Enrico Garcia, M.D.  
V (812) 462-3428  
F (812) 234-1010

## District 9

### Vanderburgh County Department. of Health

1 NW Martin Luther King Jr Blvd Rm 127  
Evansville, IN 47708-1828  
John A Heidingsfelder, MD  
V (812) 435-5684  
F (812) 435-5612



## District 3

### Fort Wayne-Allen Co Hlth Dept

1 E Main St 5th Fl  
Fort Wayne, IN 46802-1810  
Deborah McMahan, MD  
V (260) 449-7561  
F (260) 427-1391

## District 6

### Delaware County Health Department

100 W Main St Rm 207  
Muncie, IN 47305-2874  
Donna A Wilkins, MD  
V (765) 747-7721  
F (765) 747-7747

## District 5

### Marion County Health Department

3838 N Rural St  
Indianapolis, IN 46205-2930  
Virginia A Caine, MD  
V (317) 221-2000  
F (317) 221-2307

## District 8

### Clark County Health Department

1216 Akers Ave  
Jeffersonville, IN 47130-3719  
Kevin R Burke, MD  
V (812) 282-7521  
F (812) 288-2711

## District 7

### Lawrence County Health Department

2419 Mitchell Rd  
Bedford, IN 47421-4731  
Alan Smith, MD  
V (812) 275-3234  
F (812) 275-1094

<b>District</b>	<b>District Population</b>	<b>District Sq. Miles</b>	<b>Site City miles to Indianapolis</b>
District 1	675,971	1877	Valparaiso – 134
District 2	735,463	3613	South Bend – 138
District 3	687,581	4337	Fort Wayne – 118
District 4	342,606	3867	Lafayette – 63
District 5	1,474,128	3070	Indianapolis – 0
District 6	661,129	4396	Muncie – 60
District 7	334,618	3841	Bedford – 71
District 8	489,300	4161	Jeffersonville – 118
District 9	455,486	4316	Evansville – 162
District 10	224,203	2390	Terre Haute - 70

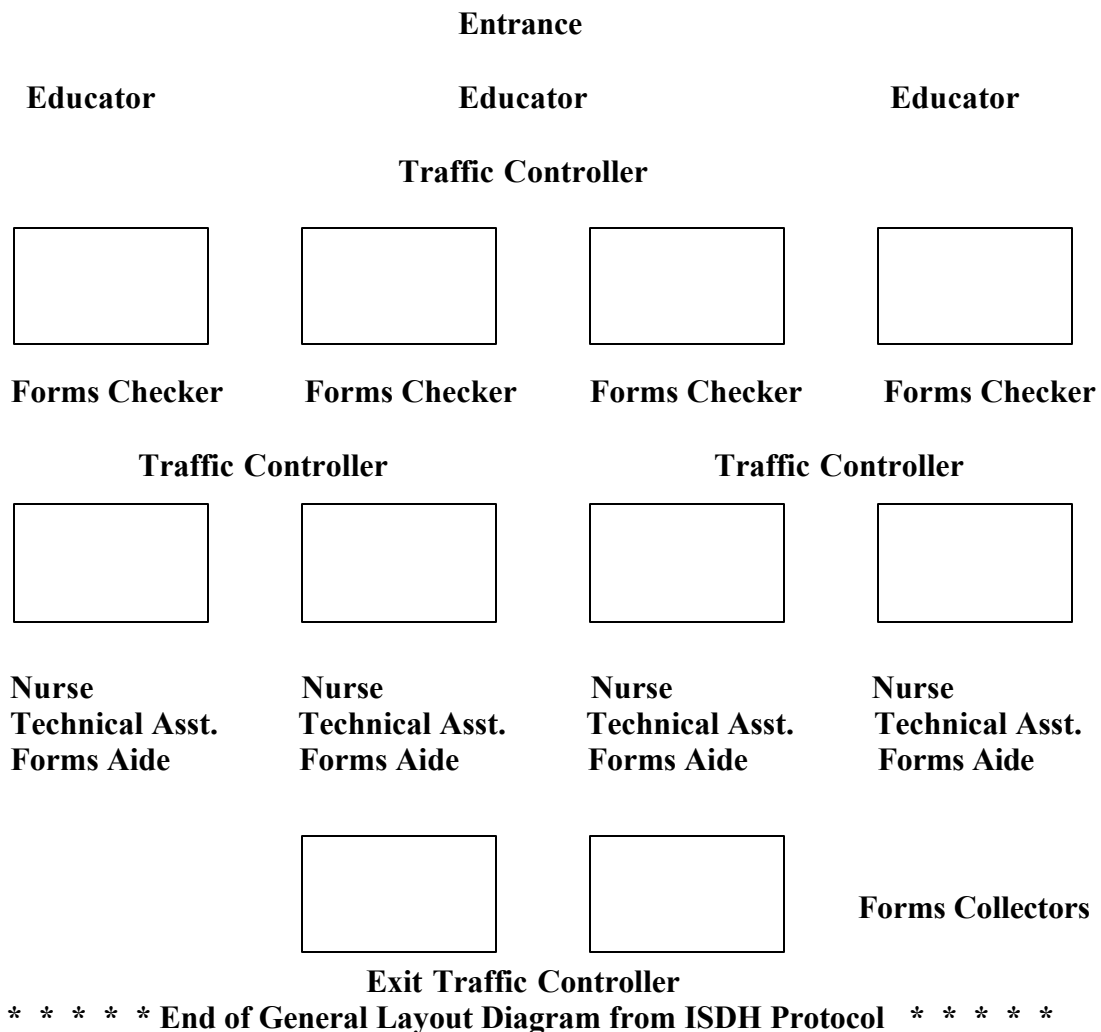
## 7. Clinic Operations & Management

a) Essential clinic functions:

Overall organization - In the summer of 2001, the ISDH released to all Indiana local health departments (LHDs) the document, *Protocol for Mass Prophylaxis*. The protocol, which is also available on the ISDH Web site, is generic to any mass prophylaxis effort but lends itself well to the present task of pre-event smallpox vaccination of several hundred persons per each of the 10 Bioterrorism Preparedness Districts in Indiana. Included in the protocol were appendices that related to clinic layout shown below which can be modified for individual clinics as needed:

**\* \* \* \* \* Beginning of General Layout Diagram from ISDH Protocol \* \* \* \* \***  
**ISDH Mass Prophylaxis Protocol: Suggested Clinic Layout**

*Public transportation, parking, zigzag lines, security personnel*



The currently available CDC Pre-event planning guidance is being used to provide specifics to LHDs. ISDH staff have provided the entire CDC guidance for Pre-event planning to all LHDs. In addition, Annex 3, “Smallpox Vaccination Clinic Guide,” has been abstracted into a two-page checklist format for use as a planning guide by the Coordinating LHDs (i.e. the LHD in each district that has assumed responsibility for clinic operation).

\* \* \* \* \* **Beginning of Planning Guide for LHDs** \* \* \* \* \*

**Abstract of CDC *Smallpox Vaccination Program Guidance***

**Annex 3 “Smallpox Vaccination Clinic Guide”**

Section	Page #	Planner	Status
Introduction <ul style="list-style-type: none"> <li>Five Considerations for Voluntary, Pre-event Vaccination</li> </ul>	B1-2		
Federal Resources through ISDH to LHDs* <ul style="list-style-type: none"> <li>Vaccine, diluent, bifurcated needles</li> <li>Vaccine administration directions</li> <li>Clinical Protocols and Support material (English and Spanish)</li> <li>Vaccine Immune Globulin (VIG) and Cidofovir (antiviral)</li> <li>Technical Assistance</li> </ul>	B1-3		
Vaccine Formulations – Dryvax in 100 dose vials stored at 2 to 8 ° C, reconstituted in 0.25 ml diluent*	B1-3		
Security Considerations <ul style="list-style-type: none"> <li>Storage sites</li> <li>Backup Power</li> <li>Clinic Sites</li> <li>Transport</li> </ul>	B1-3		
Vaccination Clinic Organization and Staffing Recommended Estimated rates per patient for clinic operation (screening 20 min, vaccination 3-5 min) <ul style="list-style-type: none"> <li>18 types of staff positions</li> <li>Roles for staff positions</li> </ul>	B1-4 B1-5 B1-6		
Considerations for Vaccine Non-Takes and Adverse Events <ul style="list-style-type: none"> <li>Hotline for reporting and handling non-takes*</li> <li>Hotline for reporting, evaluating and treating adverse events*</li> </ul>	B1-7		
Additional considerations <ul style="list-style-type: none"> <li>Referral testing for HIV &amp; pregnancy (off-site, on-site)</li> <li>Waste disposal</li> <li>Rest area for staff</li> <li>Transportation for staff</li> </ul>	B1-7 B1-8		
Public Announcements – Assisted by ISDH Public Affairs* <ul style="list-style-type: none"> <li>Uniform messages on national TV/radio</li> <li>Use of non-English speaking media</li> <li>Messages</li> <li>Pre-Event information on preparedness activities</li> </ul>	B1-8		





“Proof of Vaccination”*) • Post vaccination review			
Forms* for Smallpox Vaccine Clinics Information Sheets	B1-12 B1-26		
Clinic Preparation *Checklists	B1-36		

\* = Assistance or provision by ISDH

\* \* \* \* \* **End of Planning Guide** \* \* \* \* \*

In addition to the above planning guide, ISDH prepared a detailed one-page Table of contents format from Annex 6, “Pre-Event Vaccination Application Functional Requirements and Process Flows Version 1.1”. Included are references to the convenient Flow Chart on Page 7 of the Annex as well as to the convenient bullet-pointed lists outlining activities at each clinic station.

\* \* \* \* \* **Beginning of Summary of Annex 6** \* \* \* \* \*

**Abstract of CDC *Smallpox Vaccination Program Guidance***  
**Annex 6 Smallpox Vaccination**

This Annex contains detailed information about the data systems to be used during the management of pre-event vaccination clinics. There are also useful diagrams and lists that clinic planners might find generally helpful. The table gives an overview of Annex 6 sections.

<b>Annex 6 Page #</b>	<b>Section Description</b>
7	<ul style="list-style-type: none"> <li>• A diagram in Section 3 shows the major steps in conducting a clinic beginning with the Eligible Candidates (i.e. potential vaccinees) and ending with the “Take” Reading on Day 7</li> <li>• Diagram could be enlarged to share with clinic planners as an overview of key steps (note that the numbers in the boxes refer to the data entry mechanisms)</li> </ul>
7-8	<ul style="list-style-type: none"> <li>• See 3.1 “Overview” for a brief description of each major step in clinic function</li> <li>• Helpful, brief summary of clinic activities</li> </ul>
9	<ul style="list-style-type: none"> <li>• See Section 3.2.2 for convenient summary of Pre-Vaccination Identification of Eligible Candidates</li> <li>• Note role for hospitals</li> </ul>
11	<ul style="list-style-type: none"> <li>• See Section 3.3.2 for convenient summary of the first steps in working with “Eligible Candidates”</li> <li>• Begins with their arrival for their appointment at the clinic</li> <li>• Ends with the review of each individual’s medical history</li> </ul>
13	<ul style="list-style-type: none"> <li>• See Section 3.4.2 for continuation of potential vaccinees’ progress through the clinic</li> <li>• Begins with submission of each individual’s demographics</li> <li>• Ends with data entry of this information</li> </ul>
16	<ul style="list-style-type: none"> <li>• See Section 3.6.2 for handling of vaccine “batches”</li> <li>• Describes the record keeping necessary to provide details on diluent Lot # and Vaccine Lot #</li> </ul>
17	<ul style="list-style-type: none"> <li>• See Section 3.7.2 for generating of the call-back for “Take” ( Day 7)</li> </ul>
15	<ul style="list-style-type: none"> <li>• See Section 3.5.2 for Reading of “Take” on Day 7</li> </ul>

(note page out of order)	<ul style="list-style-type: none"> <li>Provides details about monitoring of those showing no “Take”</li> </ul>
18	<ul style="list-style-type: none"> <li>See Section 3.8.1 for diagram showing Adverse Events Record Keeping</li> <li>See 3.8.2 for the interactions between clinic staff and vaccines via a 28 Day Diary and subsequent reports to CDC</li> </ul>
19-20	<ul style="list-style-type: none"> <li>Gives descriptions of reports needed from clinics</li> <li>Details the type of reports provided by CDC</li> </ul>
21	<ul style="list-style-type: none"> <li>Details on Medical History form for each vaccinee</li> </ul>

\* Assistance or provision by ISDH

\* \* \* \* \* **End of Summary of Annex 6** \* \* \* \* \*

The above overview documents from Annex 3 and Annex 6 of the CDC guidance will help guide the Coordinating LHDs in their planning.

Clinic Details – In general, the clinics and evaluation of vaccinees post-vaccine will be shared by three entities:

- Indiana State Department of Health (ISDH)
- Coordinating Local Health Department (LHD)
- Workplace (either hospital or local health department)

Briefly, on-site operation of the clinics will be the responsibility of the Coordinating LHD in partnership with other LHDs within the district. Because of the need for medical equipment and medical expertise, most vaccination clinics will be placed at participating hospitals. At least two ISDH staff will be on-site also: a systems analyst will help assure data entry runs smoothly, and an ISDH nurse vaccinator will help with the vaccination stations. Wound care, daily inspection of vaccination site, change of dressing, and “Take” evaluation on Day 7 will all be conducted by infection control or occupational health professionals at the participating hospitals or by nurses from participating LHDs. The following table provides a summary of the function and the entity responsible:

Function	Responsibility	Function	Responsibility
1. Patient flow	Flow diagrams provided*	10. Vaccination technique	CDC/ISDH trainings
2. Record keeping	ISDH staff will assist*	11. Acute reaction management	LHD recruits local medical staff
3. Screening vaccinees	See Section b. below	12. Data collection	ISDH staff assist*
4. Security	LHD arranges	13. Vaccine accountability	LHD/ISDH assures
5. Educational materials	ISDH provides*	14. Wound management	Workplace evaluation
6. Forms	ISDH provides*	15. Waste disposal	ISDH provides bags
7. Medical supplies	ISDH provides* (See	16. Advice on adverse	ISDH recruits/trains

	Section c. below)	events	medical specialists*
8. Safety	LHD provides*	17. Vaccines' cards	LHD distributes
9. Vaccine handling	ISDH/LHD assures	18. "Take" evaluation	Workplace evaluation

\* = Assistance or provision by ISDH

#### Training for vaccination clinic staff

ISDH staff will provide training for Functions #2, #8, #9, #12, #13, #14, #16, #18. In addition all vaccinators will have special training sessions to master technique. See Part 9 for details.

#### b) Describe screening process

ISDH staff have prepared a *Decision-making Guide for Prospective Members of Indiana's Smallpox Response Teams*. This two-page Guide gives a brief discussion of the expected duties of team members as well as an overview of contraindications for vaccination (See next page).

\* \* \* \* \* **Beginning of Guide** \* \* \* \* \*

***Decision-making Guide for Prospective Members  
of Indiana's Smallpox Response Teams***

Thank you for considering the invitation to become part of a Smallpox Response Team. Invitations to join teams are being offered to those who would perform the following functions should there ever be an outbreak of smallpox:

1. Conduct epidemiologic investigation of initial cases and contact tracing of exposed persons
2. Provide care for smallpox patients
3. Conduct mass vaccination clinics

Members of Smallpox Response Teams will be expected to accept one of the above assignments for 12 hr, 7-day shifts between 1 and 3 weeks after initial cases. After that period, additional responders will be successfully vaccinated and can safely accept such assignments for more normal scheduling.

In order to become a member of a Smallpox Response Team, individuals must be vaccinated. The Centers for Disease Control and Prevention (CDC) will be releasing vaccine to Indiana in the next few weeks. The vaccine is a live *Vaccinia* virus, the same strain as that used in the US during the 1960's when universal vaccination was in practice. Accordingly, there is a wealth of information about the nature of side effects, some of which are serious. Therefore, it is important to consider any factors that might indicate risks for an individual being vaccinated.

This guide is designed to help you with a preliminary decision about being vaccinated. It should not be taken as direct and personal medical advice, but it should help you weigh the pros and cons as you are making your decision. You may also wish to consult with your personal physician. If after reviewing the following questions you are interested in becoming a team member, you will receive more details about the vaccine and the vaccination procedures. Your final decision to participate as a team member, therefore, will consist of your willingness to give an "Informed Consent" for vaccination after you have considered all details.

### **Vaccination History**

Individuals previously vaccinated without serious reactions are likely to be successfully vaccinated again unless other health conditions (itemized below under "counterindications") have developed in the meantime. Note that previous vaccination administered more than 2 years ago must be repeated to assure full protection.

- ☐ Have you received smallpox vaccination with demonstrated "Take" (i.e. a small scar is present at the site, usually the upper arm deltoid region or the upper anterior thigh)?

### **Counterindications for Smallpox Vaccination**

Based on past experience, several health conditions are well known to increase the likelihood of adverse results should there be smallpox vaccination without ready access to Vaccinia Immune Globulin (VIG). Because the national supply of VIG is not sufficient to protect large numbers of persons, anyone with the following conditions should exclude themselves from participation in a Smallpox Response Team.

- ❑ Do you have any of the following conditions?
  1. Immune suppression such as HIV infection, organ transplantation, current treatment for cancer, high dose steroid administration, or allergic to polymyxin, streptomycin, neomycin, tetracycline or sensitive to phenol
  2. Eczema or other recurring dermatological conditions (e.g. repeated occurrences of red, scaling patches of skin lasting more than one week)
  3. Pregnancy or expectation of becoming pregnant

### **Household and Workplace Situation**

Because the vaccine is a live virus, other persons may be at risk of secondary infection if they come in contact with the lesion at the vaccine site or with a bandage discarded when the dressing is changed. Vaccinated individuals will receive detailed instructions about how to care for the vaccination site until healing is completed and the scab has been discarded (about a 3 week period). However, to assure safety of others, consider the following questions.

- ❑ Do any members of your immediate household have the types of conditions listed under “Counterindications”? (Note: reactions to antibiotics or to phenol are not relevant)
- ❑ Does your current primary work responsibility place you in direct contact with any patients with “Counterindications”? (Note: reactions to antibiotics or to phenol are not relevant)

### **Ability to Function as a Member of a Smallpox Response Team**

Team members will be expected to accept assignments during the early weeks following a smallpox outbreak. Liability coverage will be provided to all practitioners. Detailed training opportunities will be offered to all team members to assure they have the knowledge and skills required to accept their assignments. (Note, costs for services, if appropriately documented during a declared emergency, can be submitted for federal reimbursement).

- ❑ Are you willing to accept a team assignment that will require you to work 12 hr, 7-day shifts for one to three weeks following initial cases of smallpox?

### **Next Steps**

After you have considered carefully the information provided in this guide, please let us know by December X, 2002, whether or not you are interested in becoming a member of one of Indiana’s Smallpox Response Teams. Contact XXXX via e-mail (addressXXX) or by phone (numberXXX).

\* \* \* \* \* **End of Guide** \* \* \* \* \*

The above Guide is designed for LHDs and hospitals who wish to use it in introducing to prospective team members the invitation to be vaccinated and to be part of the initial response should there be cases of smallpox in Indiana. Through use of the Guide,

interested professionals can be supported in a preliminary decision to participate. Those who wish to continue then receive the much more detailed education, screening, and informed consent process as they report for their clinic appointments.

c) Plans for adequate supplies and other materials

Another form of assistance for the Coordinating LHD will be “Clinic Kits,” which will be prepared by the ISDH and delivered to each clinic site. These will contain many of the expendables listed in the “Supply and Equipment Checklist” of Annex 3 (Page Guide B1-39). Provision of several of these supplies will lighten the burden of the local clinic sponsors, both with respect to planning activities and to cost.

**Listing of Clinic Supplies and Equipment**  
**(Note items to be provided in ISDH “Clinic Kits”)**

Category	Items	
Equipment	Copier FAX Machine Computers or laptops* DVD or VCR players	Large-Screen televisions Cell phones Handheld radios
General Supplies	Tables and chairs Water and cups Paper, pens, pencils Envelopes Rubber bands Tape Stapler/staples, paper clips Scissors Post-It notes Paper towel and tissues	File boxes* Telephone table pads and clean paper Garbage containers Trash bags, Biohazard* ID badges for staff* Copies of video* Food & drink for staff List of emergency phone #s Cleaning supplies
Traffic Control	Queue partitions	Signs* for site designation & clinic flow
Vaccine Administration Supplies	Smallpox Vaccine* Vaxicools/Refrigerator Vaccine diluent* Sterile bifurcated needles* Sharps containers* Latex-free gloves* Anti-bacterial hand washing solutions	Acetone Rectangle Band-Aids Gauze* Adhesive tape* Semipermeable dressing* Spray bottle of bleach solution Paper gowns Vaccination screens
	Standing orders for emergencies “Code” kit with defibrillator Medications and supplies for management of anaphylactic shock Blood pressure cuffs (Various Sizes)	Tongue depressors Emesis basins Adult pocket masks with one-way valve Adult and pediatric airways Tourniquet

	IV solution & IV solution tubing Aspirin, Tylenol, regular insulin, D50 Asthma inhaler Thermometer Oxygen tank and tubing	Gurney Stethoscope Flashlight Cots, blankets, & pillows ER report form
Packets	Consent forms*	Vaccination cards*

\* = To be supplied by ISDH “Clinic Kits”

- d) Timeline for implementing clinic operations – note the requirement for completion of vaccination within 30 days’ of announcement

As is described in greater detail in Part 5 above, the most likely scheduling of clinics and their operations will be in the first week of receiving the vaccine and again in the third and fourth weeks. An ISDH site-visit will occur at least one day before clinic operation. This visit is designed to assure that all arrangements are in compliance with the guidance provided in CDC Annex 3 and that planners have taken into account the logistics necessary for successful completion of the vaccinations scheduled for that clinic site.



## 8. Vaccine Safety Monitoring, Reporting, Treatment and Patient Referral

Coordination of vaccine safety monitoring, reporting, treatment and patient referral will be the responsibility of Charlene Graves, MD, Medical Director, Immunization; Wayne Staggs, Immunization Epidemiologist; and Robert Teclaw, State Epidemiologist.

- 1. Collection of patient vaccination data through the PVS.** Each vaccination clinic will have a functioning PVS. All smallpox vaccinees in Indiana will appear in the PVS.

Action step: Coordinate with clinic operations team to ensure that plans exist for a functioning PVS.

- 2. Medical evaluation of person with suspected adverse events.** Dressing changes and, therefore, adverse event evaluations will be performed daily by occupational health or infectious disease control personnel in hospitals and perhaps by other designated persons in local health departments (LHD). The most recent evaluation algorithms will be downloaded daily from the CDC Web resources site by the evaluators.

Action steps: Identify in each participating hospital and all LHDs the person(s) responsible for dressing changes and adverse event evaluation. Ensure that these persons have been trained in proper dressing change techniques, recognition of adverse events, downloading daily algorithm updates, and reporting protocols.

- 3. Hospital assigned physicians.** Each hospital associated with a Phase 1 vaccination clinic will identify one or more HAPs to receive referrals of adverse events from **2**. Adverse events in contacts of primary vaccinees will also be HAP responsibilities.

Action steps: Identify the HAPs. Train the HAPs in adverse event confirmation and treatment using Web-based protocols and algorithms and, when necessary, consultation with CISA. Ensure that all evaluators in **2**. know who the appropriate HAP for their area is.

- 4. Consultation with medical experts for evaluation and management of serious, unusual, or complex adverse events.** HAPs will contact CISA through a 24/7 toll-free number for assistance in handling difficult or non-routine adverse events.

Action steps: Ensure that HAPs have contact information for CISA. Develop a protocol for comparing reports from CISA with adverse event reports on the PVS.

**5. CISA will make recommendations to CDC for treatment of patients with VIG and/or cidofovir.**

Action step: Ensure that HAPs understand the protocol for obtaining VIG and cidofovir.

**6.-9. (Require no specific action steps.)**

**10. Reports of adverse events to VAERS.** In addition to tracking adverse events in PVS, reports to VAERS will be made by HAPs.

Action step: Inform HAPs of their responsibility to report adverse events to VAERS also.

**Other action steps:**

In cooperation with the ISDH Office of Legal Affairs, arrange for adverse events from vaccinia to be declared reportable by the Board of Health.

Create a list of medical experts to advise health care providers on evaluation of adverse reactions and effective medical response. Distribute the list to HAPs, LHDs, and others.

## **Section 9 - Education and Training Pre-Event Plan**

### **I. Trainers**

The ISDH has identified thirteen (13) nurses and other medical care providers who have experience in administering the smallpox vaccine. These individuals will be scheduled to attend a two-hour review session of technique and procedures to assure that all trainers are current on skills. Prior to the review session, each trainer will be provided a manual of information and will be required to view the videos (please refer to the section on Educational Materials that follows) on smallpox administration.

Upon completion of the review session, one trainer will be assigned to each district (total of 10 in Indiana) to train vaccinators and other pre-event clinic staff. Trainers will review the essential information that each local district team will need to conduct clinic and follow-up, will demonstrate the smallpox administration technique, and will observe local pre-event clinic nurses in administration of the smallpox vaccine.

### **II. Trainees**

Each local district in Indiana will identify a vaccination clinic team. Teams may consist of medical and non-medical health care providers and hospital personnel. Once the team members have been confirmed, the ISDH will provide a manual of information for review prior to any on-site training. Trainees will be nurses, physicians, medical screeners, clinic managers, health educators, and others included on the local teams.

### **III. Educational Materials for Districts**

The ISDH will provide a variety of materials for both trainers and trainees. Materials will consist of written documents compiled by the Centers for Diseases Control and Prevention (CDC); videos produced by the CDC following the December 5, 6, 2002, satellite conference; a video produced by Charlene Graves, MD, Communicable Disease Medical Director, ISDH; and a listing of World Wide Web sites to access additional information.

All written materials will be compiled in a smallpox clinic administration manual. A minimum of five copies will be distributed to each local district. One set of videos will be provided to each district.

### **IV. Educational Materials for Physicians and Nurses**

On its Web site, the Indiana State Medical Association (ISMA) has educational tutorials on all the bioterrorism diseases. The ISMA will add detailed materials specific to smallpox to this Web site. The ISMA liaison based at the ISDH will facilitate the on-line addition of the smallpox education for physicians.

The Sigma Theta Tau International (STTI) (international nursing honorary association), based in Indianapolis, has an educational Web site for nurse members. The ISDH will ask STTI to add the educational tutorial on smallpox to its Web site.

#### V. Educational Materials for Hospitals

Indiana has 131 acute care hospitals. Each hospital will receive a copy of the CDC Bioterrorism Update: Smallpox Preparedness video. The ISDH will ask the Indiana Hospital&Health Association (IHHA) to distribute one smallpox video per hospital. The ISDH will ask the IHHA to include a letter with the video, urging each hospital's Chief Executive to arrange for hospital staff to view the video. The ISDH will ensure that each hospital Staff Development Coordinator receives a copy of the smallpox clinic administration manual being distributed to the 10 districts.

#### VI. Schedule of District Trainings

December 3, 2002	Via the Indiana Higher Education Training System (IHETS) network, conduct an education session for all local health departments on smallpox administration presented by Charlene Graves, MD, Communicable Disease Medical Director, ISDH
Week of December 9, 2002	Compile and send Smallpox Clinic Administration Manual to local districts
Week of December 16, 2002	Vaccination administration training at CDC.
Week of December 23, 2002	Conduct review session for 13 trainers
Week of December 30, 2002	Initiate local trainings
Week of January 6, 2003	Complete local trainings

#### V. Schedule of In-house Activities

December 3, 2002	Secure order for 10 copies of Dr. Graves' presentation
December 6, 2002	Secure local order for 150 copies of CDC Bioterrorism Update: Smallpox Preparedness video
December 6, 2002	Schedule the train-the-trainer session; notify the 13 trainers
December 9, 2002	Identify specific materials to include in the Smallpox clinic Administration Manual; secure a print order for 150 copies of the manual
December 9, 2002	Contact 10 districts to identify a training date and seek their assistance in locating a training site
December 10, 2002	Contact IHHA to finalize plans for distribution of the CDC video and Manual
December 10, 2002	Arrange for ISMA to add smallpox tutorial to Web site
December 10, 2002	Arrange for STTI to add smallpox tutorial to Web site
December 12, 2002	Mail smallpox manuals and videos to the 10 districts and 131 hospitals
December 18, 2002	Confirm district training dates and sites

## **10. Data Management**

### **System Used**

The Indiana State Department of Health (ISDH) will use the CDC-developed Pre-event Vaccination System with named data.

### **Contact Person**

The contact person for the data management aspect of the ISDH pre-event smallpox plan is Sandra Webb, Director, ISDH Information Technology Services (ITS). Telephone: 317.233.7817; e-mail address: [swebb@isdh.state.in.us](mailto:swebb@isdh.state.in.us).

### **Support and Integration**

The ISDH will provide computer systems and ITS staff to set up and maintain these computer systems at each clinic site. The ISDH will also provide a trained data entry person to enter data into PVS on-site. These staff will be trained within seven (7) days of the availability of the PVS system. The ISDH will also develop a set of forms as a paper backup should electronic entry at the site become impossible.

We will continue to support VAERS as we have in the past. However, please refer to Section 8 for more information on how adverse events will be tracked in Indiana.

## 11. Communications

### A. Communication goals and objectives:

- To help communicate the reason for the pre-event vaccination program to public health response teams and health care response teams.
  - To hold a teleconference with all local health departments (already done).
  - To send information to hospitals through Indiana Hospital & Health Association (ongoing).
- To help the potential vaccinees understand the contraindications to being vaccinated in a pre-event program.
  - To produce a satellite telecast, which is archive webstreamed (already done).
  - To put detailed information and links on the ISDH Web site (already done).
- To help the public understand why this pre-event vaccination project is taking place.
  - To hold a news conference when the first vaccinations are given, in conjunction with the Marion County Health Department (plans are underway).
  - To respond to media requests for information.
  - To post all available information and links to CDC smallpox fact sheets (also in Spanish) on the ISDH Web site (ongoing).
- To assist the 10 district clinic sites in dealing with media requests.
  - To offer to have them send media requests to ISDH Public Affairs Director.
  - To post updates of statistics bi-weekly on the ISDH Web site, as data is sent to CDC.
  - To assist them in dealing with media requests/media events they wish to handle by providing communication points, video/photo release forms, and any other support we can supply.
- To help first responders who are not being vaccinated in this phase understand why they will have to wait until Phase Two.
  - To respond to calls and e-mails from first responders (ongoing).
  - To explain in press materials why Phase One deals only with public health response teams and hospital-based health care response teams.
- To help answer questions from family members of vaccinees.
  - To set up a phone bank to deal with such questions.
  - To show empathy with their concerns in public settings, like news conferences and public appearances.

### B. Key Messages

- For people for whom smallpox is recommended and their family members:  
The probability of an intentional release of the smallpox virus is low, but since the consequences of an outbreak would be great, we must be prepared. These

recommendations strengthen national and state preparedness by making licensed vaccine available to those people who would be called upon to respond to a smallpox release or outbreak. Smallpox vaccination before a confirmed smallpox case or outbreak provides public health response teams and health care response teams personal protection from smallpox disease. It thus enables them to rapidly take actions necessary to protect the public, which includes identifying people who need to be vaccinated to control the outbreak as well as establishing public vaccination clinics. By protecting those people who would be initially called upon to respond, we further strengthen our ability to protect the public and we increase the capacity and capabilities of the public health system and the nation's hospitals to respond to, and control, a smallpox outbreak.

- For people for whom smallpox is contraindicated:

Some people are at greater risk for serious side effects from the smallpox vaccine. **individuals who have any of the following conditions, or live with someone who does, should NOT get the smallpox vaccine unless they have been exposed to the smallpox virus.** Higher risk conditions are:

- Eczema or atopic dermatitis. (This is true even if the condition is not currently active, mild or experienced as a child.)
- Skin conditions such as burns, chickenpox, shingles, impetigo, herpes, severe acne, or psoriasis. (People with any of these conditions should not get the vaccine until they have completely healed.)
- Weakened immune system. (Cancer treatment, an organ transplant, HIV, or medications to treat autoimmune disorders and other illnesses can weaken the immune system.)
- Pregnancy or plans to become pregnant within one month of vaccination.

In addition, individuals should not get the smallpox vaccine if they:

- Are allergic to the vaccine or any of its ingredients.
- Are less than 18 years of age.
- Have a moderate or severe short-term illness. (These people should wait until they are completely recovered to get the vaccine.)
- Are currently breastfeeding.

During an actual smallpox attack, the picture could change dramatically. We would want to offer vaccination to anyone who had actually been exposed to the illness. No one would be excluded on the basis of the criteria listed above.

- For health care and emergency responders who are not currently eligible to receive the smallpox vaccine:

The decision has been made, and we think it is an appropriate decision, to start by vaccinating the people who would be most at risk if there were a smallpox outbreak. For one thing, there is not enough licensed vaccine for everyone. The goal is to prepare response teams of health care providers and public health workers, so they can respond quickly and safely if an actual case of smallpox is ever reported in the state. If that situation ever does arise, only those who have already been vaccinated will be able to safely vaccinate others, or provide care to patients with smallpox. By vaccinating a limited number of people in advance, we will immediately be able to begin vaccinating other emergency response personnel and members of the public – and caring for the sick. The small number

of people needed to perform those critical tasks will be able to begin right away, without taking time out to be vaccinated themselves.

- For the general public:

The probability of an intentional release of the smallpox virus is low, but since the consequences of an outbreak would be great, we must be prepared. These recommendations strengthen national and state preparedness by making licensed vaccine available to those people who would be called upon to respond to a smallpox release or outbreak. Smallpox vaccination before a confirmed smallpox case or outbreak provides public health response teams and health care response teams personal protection from smallpox disease. It thus enables them to rapidly take actions necessary to protect the public, which includes identifying people who need to be vaccinated to control the outbreak as well as establishing public vaccination clinics. By protecting those people who would be initially called upon to respond, we further strengthen our ability to protect the public and we increase the capacity and capabilities of the public health system and the nation's hospitals to respond to, and control, a smallpox outbreak. The decision has been made, and we think it is an appropriate decision, to start by vaccinating the people who would be most able to help the public if there were a smallpox outbreak. For one thing, there is not enough licensed vaccine for everyone. The goal is to prepare response teams of health care providers and public health workers, so they can respond quickly and safely if an actual case of smallpox is ever reported in the state. If that situation ever does arise, only those who have already been vaccinated will be able to safely vaccinate others, or provide care to patients with smallpox. By vaccinating a limited number of people in advance, we will immediately be able to begin vaccinating other emergency response personnel and members of the public – and caring for the sick. The small number of people needed to perform those critical tasks will be able to begin right away, without taking time out to be vaccinated themselves.

C. Protocols for meeting routine, possible daily, information demands from media:

- All media calls to ISDH will be routed to the Public Affairs Director or to the Bioterrorism Media Relations Director.
- Indiana data on vaccinations will be posted bi-weekly on the ISDH Web site, as it is sent to the CDC; reporters will be guided there by media relations persons.
- All District sites, which are local health departments, will be encouraged to send all media requests to ISDH.

D. Identification of spokespersons for media and select audience communications:

- Our media spokespersons will be: the State Health Commissioner, the State Epidemiologist, the Veterinary Epidemiologist, the Public Affairs Director, and the Bioterrorism Media Relations Director.
- Our public spokespersons will vary as needs arise, but will include the State Health Commissioner, the State Epidemiologist, the Veterinary Epidemiologist, the Medical Director for Immunizations, and others as assigned by the State Health Commissioner.



E. Detailed information on how smallpox communication materials will be disseminated to the vaccine audiences:

- Through the media:
  - One initial news conference, to be held in conjunction with the Marion County Health Department, with an accompanying news release disseminated by e-mail statewide to media, local health departments, and other partners;
  - Further news releases, as warranted, disseminated by e-mail statewide to media, local health departments, and other partners;
  - Responses to media calls to ISDH (and those forwarded to ISDH by the local health departments).
- Through the ISDH Web site:
  - A smallpox Web site, <http://www.in.gov/isdh/bioterrorism/smallpox/index.htm>, has been set up on the ISDH Web site. It will be referred to in news releases and all other written materials to be distributed;
  - That Web site contains links to CDC Web pages and has all the CDC fact sheets for the public and professionals, including those currently available in Spanish (the site is updated daily after a perusal of the CDC smallpox site).
- By E-mail and back-up Fax:
  - HAN notices, messages from the State Health Commissioner, news releases, and other pertinent messages are sent regularly to local health departments and other partners by e-mail and occasionally by back-up Fax.
  - Messages from the “Contact Us” button on our Web site’s homepage are responded to promptly by appropriate staff

F. Strategies for responding to communication crises, like severe vaccine adverse effects:

- We would employ these crisis communication strategies:
  - Adopting a policy of full disclosure about what is and is not known. Avoid being overly confident in the initial phases of an investigation. It is better to admit that something is unknown than to make firm but unfounded declarations in an attempt to provide reassurance.
  - Giving a detailed accounting of what is being done to address and counter the threat.
  - Recommending specific steps that people can or should take to protect themselves.
  - Avoiding speculation.
  - Avoiding the issuance of statements or information that is at conflict with that being provided by other government agencies.
  - Delivering information in a non-patronizing manner.
- We would follow our Crisis Communication Plan ([http://www.in.gov/isdh/bioterrorism/crisis\\_communication\\_plan.pdf](http://www.in.gov/isdh/bioterrorism/crisis_communication_plan.pdf))

## Part 12. Reporting Requirements

Twice-weekly status reports will be submitted to NIP, Data Management Division.

Action steps: Arrange with appropriate ISDH, Bioterrorism Preparedness District, and hospital staff to transmit required information on a regular basis, but no less than twice weekly. Transfer data to the form provided and transmit to the CDC on Monday and Thursday via FAX, Web, or e-mail. Institute quality control program for information collection and reporting.

## Appendix A: Microsoft Project Smallpox Pre-Event Vaccination Plan